

REMARKS

The Final Office Action dated December 8, 2010 has been received and reviewed. Claims 1-6, 8-16, 18, 20-31 and 33-41 are pending in the application. Claims 1-6, 8-16, 20, 27-31 and 35-39 are rejected. Claims 18, 27 and 35 are amended. Claim 41 is new, with the support by the paragraphs on page 16, line 25 – page 17, line 8. Claims 21-26, 33, 34 and 40 are withdrawn.

Reexamination of the claims is respectfully requested.

Applicants' invention is referred to as Carter hereinafter (WO 2005/064349).

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. The "input port" as recited in claim 35 is shown as 490 in Fig. 6. Applicants respectfully submit that the object is overcome.

Rejections under 35 USC 102

Claims 1-6, 8-10 and 12-16 are rejected under 35 USC 102(b) as being anticipated by Buechler (US 6,156,270). Applicants respectfully disagree.

Claim 1 recites "[a] detection cartridge comprising: a housing comprising an interior volume; a sensor operably attached to the housing, the sensor comprising a detection surface; a detection chamber ... and a waste chamber." Specifically, claim 1 teaches that "the detection chamber comprises a volume defined by the detection surface and an opposing surface spaced apart from and facing the detection surface, wherein the opposing surface comprises a flow front control feature that comprises one or more regions of hydrophobic material occupying a portion of the opposing surface and one or more regions of hydrophilic material occupying a portion of the opposing surface." Here, the flow front control feature locates on the opposing surface. Further, the opposing surface comprises one or more regions of hydrophobic material and one or more regions of hydrophilic material.

In support of the novelty rejection of claims 1, it is asserted that Buechler teaches a flow front control features on the opposing surface comprising one or more regions of hydrophobic material occupying a portion of the opposing surface and one or more regions of hydrophilic material occupying a portion of the opposing surface. (Office Action, page 4.) Buechler, however, teaches that "the hydrophobic surfaces opposing the diagnostic element can have a tendency to become hydrophilic as the reaction

mixture progresses through the diagnostic element." (Beucher, Col. 17 lines 24-30.) That is, the opposing surface in Buechler is a hydrophobic surface that comprises only hydrophobic material but it does not comprise hydrophilic material before reaction mixture passes the surface. Further, hydrophilic material is not an inherent feature to a hydrophobic surface. Hence, Beucher does not teach or suggest a flow front control features on the opposing surface using a combination of regions of hydrophobic and hydrophilic materials. Additionally, Buechler teaches that the use of a hydrophobic material on the opposing surface results in improved performance of the diagnostic device:

"In a preferred embodiment the surface opposing the diagnostic element 6 is hydrophobic such that the reaction mixture repels this surface. The repulsion of reaction mixture to the surface opposing the diagnostic element 6 forces the reaction mixture, and particularly the protein conjugates, to the surface where capture occurs, thus improving the capture efficiency of the components of the reaction mixture to the capture zone."

(Beucher, Col. 17, lines 17-24.) Accordingly, Buechler teaches that hydrophilic materials should not be used for the opposing surface because it would lead to diminished performance of the device (i.e., decreased capture efficiency). Therefore, Beucher does not teach each and every element of claim 1, either expressively or inherently described.

In summary, claim 1 is patentable over Buechler because Buechler does not teach or suggest a detection cartridge comprising a detection chamber with an opposing surface that includes a flow front control feature comprising one or more regions of hydrophobic material occupying a portion of the opposing surface and one or more regions of hydrophilic material occupying a portion of the opposing surface. Claims 2-6, 8-9, and 11-16 each add additional features to claim 1 and are patentable over Buechler for at least the same reasons.

Claim 41 recites the flow front control features that "further comprises at least one pair of successive bands of hydrophobic material and hydrophilic material wherein each pair of successive bands extends across a width of the detection chamber." As discussed above, Buechler teaches an opposing surface comprising only one material - hydrophobic material. (Beucher, Col. 17 lines 17-30.) It does not teach the opposing surface comprising successive bands of hydrophobic material and hydrophilic material. Therefore, claim 41 is patentable over Buechler.

Claims 27-31 and 35-39 are rejected under 35 USC 102(b) as being anticipated by Wiegner (US 4,013,722).

The amended claim 27 recites "[a] sealed module comprising: a housing comprising an exit port and a sealed interior volume; an exit seal located over the exit port; a first chamber located within the interior volume of the housing, the first chamber comprising a liquid located therein; a second chamber located within the interior volume of the housing, the second chamber comprising a reagent located therein; an inter-chamber seal isolating the second chamber from the first chamber within the housing; a plunger, wherein the first chamber, the inter-chamber seal, the second chamber, and the exit seal are located between the plunger and the exit port, and wherein the plunger is movable from a loaded position in which the plunger is distal from the exit port to an unloaded position in which the plunger is proximate the exit port; and an input port in fluid communication with the first chamber, wherein the input port allows material to enter the first chamber when the plunger is in the loaded position; wherein movement of the plunger towards the exit port opens the inter-chamber seal such that the liquid in the first chamber contacts the reagent in the second chamber, and wherein further movement of the plunger into the unloaded position opens the exit seal such that the liquid and the reagent from the interior volume of the housing exit through the exit port."

Wiegner teaches a sealed container with frangible partition for storing and mixing. (See Wiegner Col. 1, lines 11-21.) The container may have two compartments with a foil as a seal in between; each compartment is preloaded with material. (See Wiegner, Col. 2 lines 38-53.)

Wiegner does not teach or suggest an input port that allows material, such as a collected specimen or sample material (See Carter, pp. 29 lines 15-19). Contrarily, each compartment of the container in Wiegner is loaded with material and sealed when the container is assembled. (See Wiegner, Col. 2 lines 38-53.) Therefore, Wiegner does not teach or suggest each and every element in claim 27. Claim 27 is patentable over Wiegner.

Claims 28-31 add additional features to claim 27 and are patentable over Wiegner for at least the same reasons.

The amended claim 35 recites "[a] module comprising: a housing comprising an exit port and a sealed interior volume; an exit seal located over the exit port; a chamber located within the interior volume of the housing, the chamber comprising one or more

reagents located therein; a plunger movable from a loaded position in which the plunger is distal from the exit port to an unloaded position in which the plunger is proximate the exit port; and an input port in fluid communication with the chamber, wherein the input port allows material to enter the chamber when the plunger is in the loaded position; wherein movement of the plunger towards the exit port opens the exit seal such that material from the interior volume of the housing exits through the exit port."

The MPEP states, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP § 2131, citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (Emphasis added). As discussed above, Wiegner does not teach or suggest an input port that allows material, such as a collected specimen or sample material (See Carter, pp. 29 lines 15-19). Contrarily, each compartment of the container in Wiegner is loaded with material and sealed when the container is assembled. (See Wiegner, Col. 2 lines 38-53.) Therefore, Wiegner does not teach or suggest each and every element in claim 35. Claim 35 is patentable over Wiegner.

Claims 36-39 add additional features to claim 35 and are patentable over Wiegner for at least the same reasons.

Rejection under 35 USC 103

Claim 11 is rejected under 35 USC 103(a) as being unpatentable over Buechler. Claims 18 and 20 are rejected under 35 USC 103(a) as being unpatentable over Buechler in view of Wiegner (US 4,103,772). Applicants respectfully disagree.

As stated by the Board of Appeals and Interferences in *Ex Parte Karoleen B. Alexander* (Appeal 2007-2693, Application 10/757,116, Decided November 30, 2007, 2007 WL 4239164), "[o]bviousness requires a suggestion of all the elements in a claim (citing *CFMT, Inc. v. Yieldup Int'l Corp*, 349 F. 3d 1333, 1342 (Fed. Cir. 2003) and 'a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does' (citing *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007)." See *Ex Parte Alexander* at 3, emphasis added.

Applicants respectfully assert that Buechler collectively do not teach or suggest, as discussed above, at least the element of "a detection chamber located within the

interior volume of the housing, wherein the detection chamber comprises a volume defined by the detection surface and an opposing surface spaced apart from and facing the detection surface, wherein the opposing surface comprises a flow front control feature comprising one or more regions of hydrophobic material occupying a portion of the opposing surface and one or more regions of hydrophilic material occupying a portion of the opposing surface." Contrarily, Buechler teaches that the use of a hydrophobic material on the opposing surface results in improved performance of the diagnostic device. (Beucher, Col. 17, lines 17-24.) Thus, Buechler teaches that hydrophilic materials should not be used for the opposing surface because it would lead to diminished performance of the device (i.e., decreased capture efficiency).

For at least the reasons described above, a *prima facie* case of obviousness has not been established with respect to claim 11, and the rejection of claim 11 under 35 U.S.C. § 103(a) over Buechler has been overcome and should be withdrawn.

Similarly, the amended claim 18 is patentable over Buechler in view of Wiegner because Buechler and Wiegner does not or suggest, at least the element of "a detection chamber located within the interior volume of the housing, wherein the detection chamber comprises a volume defined by the detection surface and an opposing surface spaced apart from and facing the detection surface, wherein the opposing surface comprises a flow front control feature comprising one or more regions of hydrophobic material occupying a portion of the opposing surface and one or more regions of hydrophilic material occupying a portion of the opposing surface."

For at least the reasons described above, a *prima facie* case of obviousness has not been established with respect to claim 18, and the rejection of claim 18 under 35 U.S.C. § 103(a) over Buechler in view of Wiegner has been overcome and should be withdrawn. Claim 20 adds additional features to claim 18 and are patentable over Beuchler in view of Wiegner for at least the same reasons.

All outstanding objections and rejections are believed to have been met and overcome. If a telephonic conference with Applicants' undersigned representative would be useful in advancing the prosecution of the present application, the Examiner is invited to contact the undersigned at (651) 575-3644. A notice of allowance for all pending claims is respectfully solicited.

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